

Curriculum Vitae
ELDON H. NYHART, JR.

Education

Ph.D., Biopharmaceutics and Pharmacokinetics, 1984
Department of Industrial and Physical Pharmacy
School of Pharmacy and Pharmacal Sciences
Purdue University, West Lafayette, IN 47907

B.S., Biomedical Engineering, 1978
Department of Biomedical Engineering
School of Engineering
Vanderbilt University, Nashville, TN 37240

Affiliations/

Awards National Merit Letter of Commendation, Rho Chi Honor Society, David Ross Fellow, Sigma Xi Scientific Research Society, American College of Clinical Pharmacology, American Society for Clinical Pharmacology and Therapeutics, American Association of Pharmaceutical Scientists, Indiana Health Industry Forum.

Background

1978-79 Ultrasound Research Assistant, Indianapolis Center for Advanced Research, Indiana University Medical Center, Indianapolis, Indiana.
1979-80 Research Assistant, Department of Industrial and Physical Pharmacy, School of Pharmacy and Pharmacal Sciences, Purdue University, West Lafayette, Indiana.
1980-84 Teaching Assistant, Research Assistant, Research Fellow, Department of Industrial and Physical Pharmacy, Purdue University.
1985-97 Instructor, Department of Pharmacology and Toxicology, Department of Clinical Pharmacology, Indiana University School of Medicine, Indianapolis, Indiana.
1984-98 Scientist, Eli Lilly and Company, Indianapolis, Indiana.
1998- President, Biosynergetics, Inc., Zionsville, Indiana.

Extensive 20 year experience with all manner of absorption, distribution, metabolism, elimination and effects associated with chemical entities in biological systems, as well as applied clinical pharmacology and industrial pharmaceutics.

- Collaborated on the conduct, protocol fabrication and final report production for Preclinical, Phases I, II, III and IV of drug development.
- Performed pharmacodynamic data analyses, dose-effect, and dose-response modeling.
- Provided pre-clinical data evaluation and extrapolation to man, species scale-up, and population pharmacokinetic data analysis and modeling.
- Reviewed drug dissolution and correlation analyses, drug dosage-form design and formulation development data.
- Furnished collection and analysis procedures for various types of biomedical measurements, biological sample handling, and analytical assay methodology design and development.

- Developed pharmacodynamic and pharmacokinetic data acquisition methods and analytical methodology with incorporation into clinical protocol designs through clinical database design necessary to support data analysis.
- Prepared and reviewed IND and NDA submission documents.
- Corresponded with the FDA on matters other than standard submission documents.
- Completed numerous final clinical study reports with submission to the FDA.
- Authored or coauthored professional journal publications.
- Provided drug package insert preparation and updating to the FDA.
- Performed pharmacokinetic and statistical data analysis and evaluation using various mathematical modeling and statistical computer software packages for submission to the FDA.
- Designed radiocarbon studies, dose escalation studies, drug-drug interaction studies, mass balance and metabolite identification studies and analysis, and large scale multi-center international efficacy trials.

Post-doctoral teaching responsibilities have included graduate lecturing and instruction for The Indiana University School of Medicine Departments of Pharmacology and Toxicology, and Clinical Pharmacology. Reviewer for the Journal of Clinical Pharmacology.

Some drug classes investigated have included biosynthetic and isolated proteins and hormones, insulin-like growth factors, human growth hormones, anti-inflammatory agents, antibiotics, peripheral vasodilators, oncolytics, activated protein C, antipsychotics and psychotropic agents.

Various independent consulting engagements involving confidential company acquisitions, lawsuit support, and biotechnology contract research have been completed at Biosynergetics, Inc. Submission of several US and PCT patent and provisional patent applications supporting proprietary medical and energy technologies have been submitted in two research areas. Three US and numerous international patents have been granted arising from these application submissions and assigned to Biosynergetics, Inc., with expectation of further intellectual property allowances forthcoming.

Publications

1. Nyhart, Jr., E.H., Henry, D.P., Nell, G., Hamilton, M. and DeSante, K.A. Bioavailability and Pharmacokinetics of Pinacidil After Oral Administration of an Immediate- and Extended-Release Formulation. APhA Meeting, Minneapolis, MN, October 18-25, 1985.
2. Henry, D.P., Nyhart, Jr., E.H., and Bowsher, R.R. Pharmacokinetics of Humatrop (Biosynthetic Human Growth Hormone) in Man: IV, IM, Subcutaneous Administration. The Endocrine Society Meeting, 1987.
3. Henry, D.P. and Nyhart, Jr., E.H. Phase I Evaluation of HGH - A Selective Review. Human Growth Hormone Symposium, Miami, FL, January, 1987.
4. Nyhart, Jr., E.H., Bowsher, R.R. and Henry, D.P. An Application of System Analysis to Biosynthetic Human Growth Hormone Bioavailability and Dosing. Eli Lilly Modeling Conference, October, 1987.

5. Black, H.R., Brier, G.L., Wolny, J.D., Nyhart, Jr., E.H. Daptomycin: Dose Linearity of 2, 3, 4 and 6 mg/kg and Comparison of Serum Antibacterial Activity of Single and Divided Daily Dose. 29th ICAAC Meeting, Houston, TX, September, 1989.
6. Peyton, A.L., Ziege, E.A., Nyhart, Jr., E.H., Panetta, J.A., Phillips, M.L., McNay, J.L. The Metabolism and Disposition of ¹⁴C Tibenelast in Man After Multiple Oral Doses. 4th Annual Meeting, AAPS, October 22, 1989.
7. Henry, D.P., Bowsher, R.R., Cerimele, B.J., Nyhart, Jr., E.H. The Administration of Recombinant-Derived Insulin-Like Growth Factor II (IGF-II) to Normal Human Subjects. 72nd Annual Meeting, The Endocrine Society, June 20, 1990. Endocrine Soc. Abst. 72:1150, 1990.
8. McNay, J.L., Cerimele, B.J., Nyhart, Jr., E.H., Peyton, A.L. Synergism of Albuterol (ALB) and Tibenelast (TIB), An Inhibitor of Phosphodiesterase (PDEase). American Society for Clinical Pharmacology and Therapeutics Annual Meeting, 1990.
9. Gorski, J.C., Allerheiligen, S.R.B., Hatcher, B.L., Farid, K.Z., Farid, N.A., Nyhart, Jr., E.H., Fasola, A.F., DeSante, K.A. Population Pharmacokinetic Analysis of Indecainide in Healthy Adults. 6th Annual Meeting, AAPS, October, 1991.
10. Woodworth, J.R., Nyhart, Jr., E.H., Brier, G.L., Wolny, J.D., Black, H.R. Single-Dose Pharmacokinetics and Antibacterial Activity of Daptomycin, a New Lipopeptide Antibiotic, in Healthy Volunteers. Antimicrobial Agents and Chemotherapy, 36(2):318-325, February, 1992.
11. Oldham, S.W., DeLong, A.F., Nyhart, Jr., E.H., Schwertschlag, U.S., Hyslop, D.L. High Performance Liquid Chromatographic Determination of Duloxetine and Metabolites in Biological Samples. 23rd Ohio Valey Chromatography Symposium, Heuston Woods State Park Lodge, Ohio, June, 1992.
12. Lemberger, L., Obermeyer, B.D., Nyhart, Jr., E.H., Goldberg, M.J. The Clinical Pharmacology of LY170053, An Atypical Antipsychotic. Schizophrenia 1992: Poised for Change, Vancouver, B.C., July, 1992.
13. Obermeyer, Boyd D., Nyhart, Jr., Eldon H., Mattiuz, Edward L., Goodwin, Michael R., Barton, Richard D., Breau, Alan P., Gillespie, Todd A., Binkley, Shelly N., Rubin, Alan, Lemberger, Louis The Disposition of Olanzapine (OL) in Healthy Volunteers. The Pharmacologist, 35(3), 1993.
14. DeLong, Allyn F., Oldham, Samuel W., Nyhart, Jr., Eldon H., Hyslop, David L. HPLC Determination of Duloxetine (LY248686) and Metabolite in Humans. The FASEB Journal, 7(3)2806, February 19, 1993.
15. Woodworth, James R., Nyhart, Jr., Eldon H., Wolney, James D., Brier, Gordon L., Black, Henry R. Tobramycin and daptomycin disposition when co-administered to healthy volunteers. J. Antimicrob. Chemo., 33:655-659, 1994.
16. Patel, B. R., Goldberg, M., DeLong, A., Nyhart, E., Cerimele, B., Stowers, J. Effect of Time of Administration on Duloxetine Pharmacokinetics in Healthy Volunteers. Amer. Soc. Clin. Pharmacol. Ther., 1994.

17. Patel, BR, Nyhart, EH, Kassahun, K, Callaghan, JT, Hunt, TL, Kurtz, DL, Bergstrom, RF. Combined Population Pharmacokinetic Analysis of Olanzapine in Healthy Volunteers. *Pharm. Res.*, Oct. 1995.
18. Bergstrom, RF, Callaghan, JT, Cerimele, BJ, Nyhart, Jr, EH, Kassahun, K, Hunt, TL. Pharmacokinetics of Olanzapine in Elderly and Young. *Pharm. Res.*, Oct. 1995.
19. Nyhart, Jr, EH, Cerimele, BJ, Kassahun, K, Callaghan, JT, Bergstrom, RF, Radtke, DB. An Initial Assessment of the Bioequivalence of Capsule and Tablet Formulations of Olanzapine. *Pharm. Res.*, Oct. 1995.
20. Patel, BR, Kurtz, DL, Nyhart, Jr, EH, Kassahun, K, Callaghan, JT, Bergstrom, RF. Population Pharmacokinetics of Olanzapine in Phase II/III Clinical Trials. US Olanzapine Investigator's Meeting, Indianapolis, IN, Mar, 1996.
21. Bergstrom, RF, Callaghan, JT, Cerimele, BJ, Nyhart, Jr, EH, Kassahun, K, Hunt, TH. Pharmacokinetics of Olanzapine in Elderly and Young Subjects. . US Olanzapine Investigator's Meeting, Indianapolis, IN, Mar, 1996.
22. Nyhart, Jr, EH, Zervos, PH, Storniolo, AM. Single Dose Pharmacokinetics of a Novel Sulfonylurea (LY295501) in Cancer Patients at Various Dose Levels. ASCO Annual Meeting, Philadelphia, PA, May, 1996.
23. Bergstrom, RF, Callaghan, JT, Cerimele, BJ, Radtke, DB, Tatum, DE, Nyhart, Jr, EH, Potkin, SG. Pharmacokinetics of Olanzapine in Caucasian, Chinese, and Japanese Subjects. AAPS Abstract Pharm. Res. Oct 1996.
24. Nyhart, Jr., EH., Ease of Pharmacokinetic Evaluation Improved with New Plotting and Analysis Software. Scientific Computing and Automation, October, 1996.
25. Maya, JF, Callaghan, JT, Bergstrom, RF, Cerimele, BJ, Kassahun, K, Nyhart, Jr, EH, Brater, DC., Olanzapine and Warfarin Drug Interaction. ASCPT, 1997.
26. Callaghan, J. T., Cerimele, B. J., Kassahun, K. J., Nyhart, Jr., E. H., Hoyes-Beehler, P. J., Kondraske, G. V., Olanzapine: Interaction Study with Imiprimine, *J. Clin. Pharmacol* (37)971-978, 1997.
27. Beale, P., Judson, I., Rees, C., Trigol, J., Nyhart, E., Wolf, L., Walker, R., Moore, S., Hanwell, J., Phase I Trial JNAF of the Arylsulfonylurea LY295501 administered once daily for 5 days every 28 days. NCIEORTC, Amsterdam, June 16-19, 1998.
28. Diab, S., Baker, S.D., Hammond, L., Villalona, M., Eckhart, S.G., Tinu, C., Weiss, G., Kraynak, M., Aylesworth, C., Smith, L., Rodriguez, G., Drengler, R., Patil, R., Siu, L., Rothenberry, M., Smetzer, L., Nyhart, E., Storniolo, A., VonHoff, D., Rowinsky, E., Phase I and pharmacokinetic (PK) study JNAA of the diarylsulfonylurea LY295501 administered as a single oral dose weekly for 3 weeks, every 4 weeks. NCIEORTC, Amsterdam, June 16-19, 1998.
29. Nyhart, Eldon H., Jr., Apparatus for the controllable modification of compound concentration in a tube, International Application Published Under The Patent Cooperation Treaty WO 01/28606, October, 20, 2000.
30. Nyhart, Eldon H., Jr., Apparatus for the controllable modification of compound concentration in a tube, United States Patent Application 20020065493, May 30, 2002.

31. Nyhart, Eldon H., Jr., Manufacturing methods for an apparatus for the controllable modification of compound concentration in a tube, United States Patent Application 20020115958, August 22, 2002.
32. Nyhart, Eldon H., Jr., et al., Electromagnetic radiation collector and transport system, United States Patent Application 20030154973, August 21, 2003.
33. Nyhart, Eldon H., Jr., et al., An electromagnetic radiation collector and transport system, International Application Published Under The Patent Cooperation Treaty WO 2004/012273, February 5, 2004.
34. Nyhart, Eldon H., Jr., Apparatus and methods for the controllable modification of compound concentration in a tube, United States Patent No. 6,738,661, May 18, 2004.
35. Nyhart, Eldon H., Jr., et al., Electromagnetic radiation collector and transport system, United States Patent No. 6,957,650, October 25, 2005.
36. Nyhart, Eldon H., Jr., Apparatus for the controllable modification of compound concentration in a tube, United States Patent No. 6,985,770, January 10, 2006.
37. Nyhart, Eldon H., Jr., An electromagnetic radiation collector and transport system, United States Continuation Patent Application, January 15, 2007.
38. Nyhart, Eldon H., Jr., et al., Electromagnetic radiation collector and transport system, United States Patent No. 7,164,839, January 16, 2007.
39. Nyhart, Eldon H., Jr., et al., Electromagnetic radiation collector and transport system, United States Patent No. 7,369,735, May 6, 2008.
40. Nyhart, Eldon H., Jr., Compound Delivery Tube, United States Patent Application 20080319373, December 25, 2008.